JUN 7 - 2005

K 031196

510(k) Summary
for
Surgetics ORTHO KNEELOGICS Navigation System

1. Submitter Name and Address

Praxim
"Le Grand Sablon"
4, Avenue de l'Obiou
38 700 La Tronche
France

Contact Name: Stéphane Lavallée
Telephone: 33-4 76 54 95 03

Date Prepared: April 28, 2005

2. Device Name

Proprietary Name: Surgetics ORTHO KNEELOGICS Navigation System
Common/Usual Name: Image guided surgical navigation system
Classification Name: Computed tomography x-ray system (accessory)

3. Predicate Device

BrainLab Vector Vision CT-Free (K021306)
OrthoSoft Navitrack System-Optical TKR CT-Less (K021760)

4. Intended Use

The Surgetics ORTHO KNEELOGICS Navigation System is intended for use during stereotactic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures. It is specifically indicated for assisting the surgeon during:

- Anterior Cruciate Ligament (ACL) surgery by estimating anisometry of potential insertion points based on a digitized anatomical model
- Total Knee Arthroplasty with ZIMMER NEXGEN implant
- UniKnee Arthroplasty with BIOMET OXFORD Phase III implant

5. Device Description

The Surgetics ORTHO KNEELOGICS Navigation System (ORTHO KNEELOGICS) consists of the following major components and subsystems:

- The Surgetics Station, consisting of a mobile computer system and an optical localizer
- Ancillary instruments and reflective markers used for reference and registration
- ORTHO KNEELOGICS Navigation applications software

6. Technological Characteristics and Substantial Equivalence

The Surgetics ORTHO KNEELOGICS Navigation System is substantially equivalent to other stereotaxic instruments that have been cleared for use in knee surgery without CT imaging, including the BrainLab Vector Vision CT-Free (K021306) and the OrthoSoft Navitrack System-Optical TKR CT-Less (K021760). The ORTHO KNEELOGICS and the predicate systems all acquire positional data by tracking reflective markers and digitizing the relative locations of anatomical landmarks, and then use this data to display virtual 3D images used for subsequent planning and navigation during surgery. The three systems can all be used with different manufacturer's implant components.

7. Performance Testing

The Surgetics ORTHO KNEELOGICS Navigation System was tested for compliance with electrical safety and electromagnetic compatibility standards. In addition, summaries of accuracy testing using phantoms and specimen bench testing and results of a clinical study were provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 - 2005

Praxim
C/o Ms. Sheila Hemeon-Heyer, J.D., RAC
Medical Device Consultants Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K031196
Trade/Device Name: Surgetics ORTHO KNEELOGICS Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 28, 2005
Received: April 29, 2005

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K031196

Device Name: Surgetics ORTHO KNEELOGICS Navigation System

Indications for Use:

The Surgetics ORTHO KNEELOGICS Navigation System is intended for use during stereotactic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures. It is specifically indicated for assisting the surgeon during:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031196